Optimizing Syringes Tubs Scanning in the Aseptic Filling Area through a Portable Screen Mobile Scanning System

Mariliz Santiago Maldonado
Manufacturing Competitiveness
Rafael Nieves, Pharm.D.
Industrial and Systems Engineering
Polytechnic University of Puerto Rico

Abstract — *This research is a comprehensive study of the optimization of the syringe tubs scanning process in aseptic filling area and using the mobile scanning system to reduce lead-time and improve efficiency. Integration of DMAIC methodology as a structured procedure allows for a thorough analysis of scanning procedure during the filling process in March 2024, based on the data collected from the batches filled. The analysis includes the study of the lead times, which displays significant variation across batches, that leads to clear inefficiencies within the pre-implementation of the process The implementation of the mobile scanning system results in a significant reduction of lead-times. This demonstrates the effectiveness of optimization efforts when it comes to getting the right materials and making the best use of our resources. Standardization, automation, and the implementation of systems are crucial strategies that are needed to support these advancements and make them more productive, efficient, and profitable.*

Key Terms — *Aseptic Filling Process, Mobile Scanning System, Process Optimization, Syringes Tubs*

PROBLEM STATEMENT

In the pharmaceutical industry, the aseptic filling process is a critical part of the manufacturing process where syringes are filled with drug in a sterile environment. One of the key processes in this area is the receiving of syringe tubs from the warehouse after dispatch. This process involves scanning each tub to ensure the correct inventory is received and to track the movement of syringes throughout the facility. The current scanning of syringes tubs in the aseptic filling area is not the best option for productivity. The use of traditional handheld scanners to scan every tub manually is time-consuming and may result in delays of the receiving process. This creates operational ineffectiveness and production schedule may be affected. To address this issue and improve the timing during the receiving process after the warehouse dispatch, a mobile scanning system can be implemented. This system would involve the use of mobile scanning devices, such as smartphones or tablets, equipped with barcode scanning capabilities. These devices would be used to scan the barcode on each syringe tub as it is received in the aseptic filling area. Using a mobile scanning system, the entire scanning mechanism could be made simpler and more convenient. This would eliminate the need for manual data entry and reduce the time required to scan each tub. Additionally, the use of mobile devices would allow for real-time data capture and communication, improving accuracy and visibility into inventory levels.

RESEARCH DESCRIPTION

The Aseptic Filling is such a critical role in the pharmaceutical industry due to the high importance of keeping parenteral products completely sterile, of high quality, and of high efficacy. The optimization of the syringe tubs scanning in the aseptic filling area is of the essence to make the operations smoother, have fewer mistakes, and attain the highest production rate. This research concentrates on designing a syringe tubs mobile scanning system with DMAIC principles (Define, Measure, Analyze, Improve, and Control) to be used for scanning syringe tubs in aseptic filling area. Regarding this, the main intent is to reduce the chances of mistakes, increasing precision, and improving efficiency. Ultimately, this study will be a guarantee of patients getting safe and high-quality parenteral drugs. Furthermore, there are a number of advantages such as potential cost savings and better regulatory compliance.

Research Objectives

Using the DMAIC methodology and a mobile scanning device, the study objectives seek to optimize the syringe tub scanning process in the aseptic filling area. Finding the present inefficiencies and bottlenecks in the syringe tub scanning process is the first goal. This involves assessing the current system, comprehending the difficulties operators encounter, and identifying areas that require improvement. The development and implementation of a mobile scanning system that will improve the scanning procedure, increase accuracy, and shorten scanning times is the second goal. The final goal is to assess the mobile scanning system's efficacy based on performance.

Research Contributions

The development of the research on optimizing syringes tubs scanning will make several valuable contributions to the industry. First, the research will focus on improving the efficiency and accuracy of the scanning process in the aseptic filling area. By the implementation of a mobile scanning system, the time taken for scanning syringes tubs can be significantly reduced, leading to increased overall productivity in the pharmaceutical manufacturing process. Also, the research will address the problems that are recurring since humans are the source of errors, for instance, through scanning or data entry. The introduction of a mobile scanning system, meanwhile, can reduce the risk of errors and improve the accuracy and reliability of the scanning process.

Literature Review

In the last few years, pre-filled syringe tubs have been widely adopted in the manufacturing industry since they offer attributes like productivity, safety, and convenience. According to Sacha [1] these prefilled syringe tubs are preassembled with the necessary components including a barrel, piston, plunger rod, needle and needle shield. This eliminates the manual assembly requirements and reduces the risk of contamination. Therefore, the process becomes more linear and effective and this results into the reduction of costs and increases in the productivity. Furthermore, prefilled syringe tub recedes the need for complicated filling and weighing operations, which results in a user-friendly and ready-for-use solution. They are convenient due to their easy handling and precise dosing which makes them suitable for use in the healthcare industry. In addition, Sacha [1] mentioned that the development of syringes that are filled with drug solutions and ready to use offer multiple advantages. For example, the packaging is small which makes them to carry without requiring a lot of space for storage. This reduces waste for expensive drug solutions.

According to Parag V Ingle [2] a comprehensive environmental control system for an aseptic processing facility includes but is not limited to each production phase that has specific environmental control requirements. Agalloco mentioned that the cleaning and disinfection procedures are an important part the environmental control program [3]. Syringe tubs sanitization in the manufacturing industry is an important part of the process, which guarantees the safety and high quality of the products being produced. The syringe tubs are shipped from the warehouse, it is of great significance to sanitize them before they are used in the production process. An efficient way of sanitizing syringe tubs is by using a mixture of Sporklenz solution and 70% IPA spray. Sporklenz is a disinfectant that is commonly used in the manufacturing industry for its wider spectrum antimicrobial activity. The contact time proposed for Sporklenz is 10 minutes, this time enough for the solution to show its disinfecting properties and completely kill any pathogens that may be on the surface of the syringe tubs. The next step of the procedure is to use the Sporklenz to sanitize the syringe tubs. To eliminate any remaining bacteria or viruses, a 70% IPA spray should be applied after this. Manufacturing facilities can maintain a high standard of cleanliness and safety through implementing a sanitization process into operation.

Integrating a MES system with other devices and systems to streamline operations is one of its primary functions. To enhance inventory management and tracking, there has been an increasing tendency in recent years to connect mobile scanning devices with MES systems. Employees can quickly and simply scan barcodes or tags on materials, components, and products with mobile scanning devices, which update the MES system in real time. The manufacturing process is made more accurate, efficient, and error-free thanks to this real-time data. In addition, manufacturing operations can be made even more efficient and productive by implementing Lean principles into the utilization of mobile scanning equipment and MES systems. Lean concepts emphasize the elimination of waste, reducing down on inefficiencies in processes, and continually improving operations. As stated by Cottyn Real-time production information is crucial to make important business decisions [4]. A manufacturing execution system (MES) can provide the necessary support during the Lean journey [4]. MES can trigger, feed or validate the Lean decision-making process by providing useful information [4]. In addition, MES can maintain the process improvements by enforcing the standardized way of working [4]. However, this is only possible when MES is aligned and is kept aligned to the Lean objectives [4].

The transition between production runs for distinct products or batches is referred to as the "changeover process" in the manufacturing industry. Product changeovers are especially critical for multiproduct environments where key production system requirements are flexibility, time, and quality [5]. To guarantee that the new product is manufactured in compliance with specifications and regulations, this process involves switching out materials, equipment, and setups. The procedure of changing between lots is especially important in the pharmaceutical manufacturing industry to avoid delays, guarantee product quality, and comply with regulations. Syringe tubs scanning are a particular phase in the changeover process that involves making sure the right parts and materials are used for every production run.

METHODOLOGY

Quantitative and qualitative methodologies will be used to accomplish the research objectives. The qualitative method of this research project will involve conducting in-depth interviews with key stakeholders including operators, quality control personnel, and managers in the aseptic filling area. The interviews will be of great help to understand the existing processes and know the current problems related to scanning syringe tubs. Furthermore, the observation of the aseptic filling area operations will be done to determine the operation flow and identify critical points that can be optimized to improve operations. The data gathered qualitatively will contribute a significant understanding of the practices employed actually and will help in formulating recommendations for improving the scanning of syringe tub process.

The quantitative method employed in this research project is the collection of statistical data on how efficient and effective was the previously used syringes tubs scanning process and how the portable screen mobile scanning technology has improved its performance in the aseptic filling area. This information will acquire via observations of the scanning process, registering the time consumed in scanning on a syringe tubs and reporting any mistakes or discrepancies found in the data was reviewed in the scanned information. The data will be analyzed statistically, and the scanner accuracy and speed will be quantified to show the improvements achieved through the employment of portable screen mobile scanning system.

In order to maximize the syringe tubs scanning in the aseptic filling area, the DMAIC methodology will be used in this research project.

- **Define Phase:** The main goal is to describe the problem and set the goals of the project. This requires understanding of the current syringes' tubs scanning process in the aseptic filling area, involvement of key stakeholders, determination of the root cause of the inefficiencies or errors taking place in the current scanning system, and establishing clear measures of success. During this step, it is necessary to gather data and information related to the ongoing scanning procedure which could be mistakes faced by the operators as well as feedback by the different users.
- **Measure:** Creating a process map will allow for a quantitative analysis of the current process in order to identify the key performance indicators (KPIs) associated to the scanning of syringe tubs in the aseptic filling area. This map specifies the steps of the ongoing scanning process like syringes tubs identification, sanitization, scanning procedures, data entry, and verification. This map is aimed at displaying the problems that may arise and address any inefficiency in the process. The visualizing process serves as a bridge to clear areas needing improvement and helps set a starting point to track the progress of the optimization efforts.
- **Analyze:** The emphasis will be on studying the current process and finding areas of improvement. The investigation will mainly focus on the lead-time for tub's sanitization process and scanning. Through the time study, one will be in a better position to identify the bottlenecks and inefficiencies that exist in the workflow. Furthermore, the fishbone diagram will be used to list the root causes visually, which can slow up the scanning process.
- **Improve:** This stage incorporates modifying the existing scanning process, which includes the introduction of the portable screen mobile scanning equipment into the workflow and employees' training on how to fully utilize it. Also, it includes testing and pilot runs to make sure that the new system enhances the accuracy and efficiency of the RFID tags while scanning the syringe tubs. The monitoring and evaluating activities will be conducted on an ongoing basis to ensure that all the challenges that may occur during implementation are addressed immediately for the purpose of optimizing the scanning process in the aseptic filling area. Involving key stakeholders, such as operators, supervisors and quality assurance experts, is crucial in the Improve phase for gathering feedback on the effectiveness of the new scanning system.
- **Control:** The control phase focuses on establishing strategies to sustain the improvements achieved in the previous phases. This includes developing Standard Operating Procedures (SOPs) for the use of portable screen mobile scanning for syringes tubs, training employees on how to operate the new equipment effectively. In addition, regular audits and reviews will also be performed to identify and correct any deviations from the successful process in order to maintain efficiency and efficacy.

RESULTS AND DISCUSSION

This project aims to optimize the syringe tub scanning operation of the aseptic filling area by introducing a mobile scanning system. The main goal is to increase efficiency and precision by minimizing the workload of the scanning process. The project will include activities of researching and selecting an efficient portable scanning system, designing integration plan, checking and evaluating the system, implementing it and monitoring its performance after the implementation. Key stakeholders such as Aseptic Filling operators, Warehouse staff, Quality Assurance experts, information systems (IT) specialists for system development and management will play important roles in the project.

Define Phase

Research results related to optimizing syringes tubs scanning were collected at the Define stage of DMAIC methodology. A Project charter, shown in Figure 1 was developed to provide a 12 weeks timeline for the project to align it with the targeted outcome. This phase involves a thorough examination of the current syringes' tubs scanning process taking place in the aseptic filling area to determine its weak points and areas for improvements. It was revealed that the existing manual scanning method was slow and tedious as well as error prone, and so it was inefficient in overall production. Additionally, it was shown that by employing a portable screen mobile scanning system the scanning process could be simplified, the number of errors could be reduced and the productivity in the aseptic filling area could be increased. Operators to scan syringes tubs rapidly with a hand-held device that would eliminate data entry and greatly reduce the chance for errors could use this system.

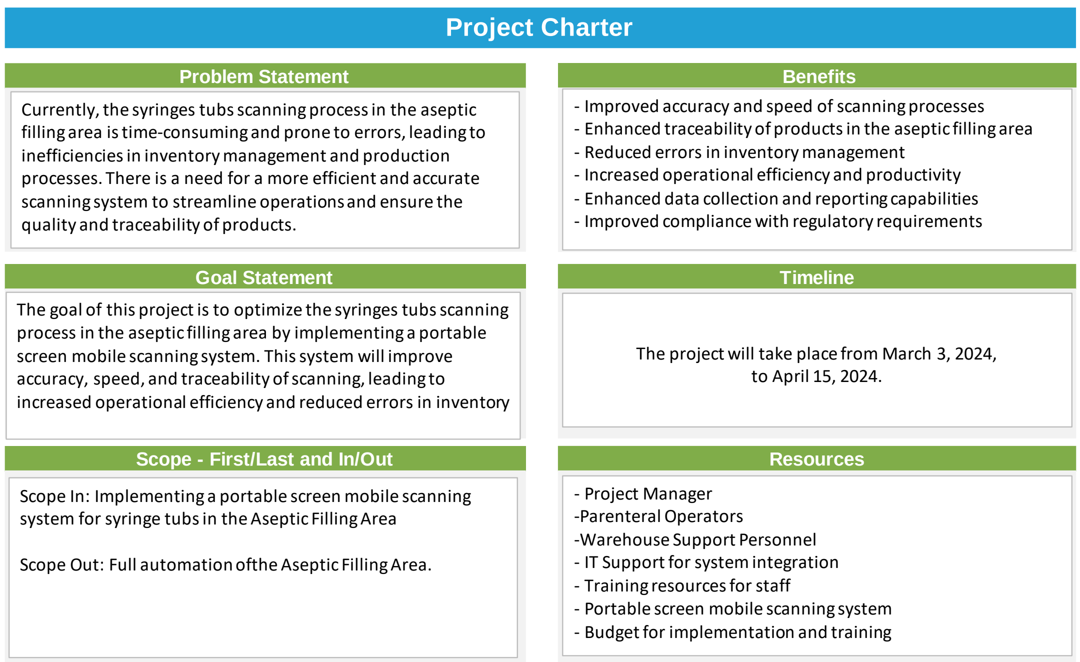

Figure 1

Project Charter about the Syringes Tubs Scanning Process

Measure Phase

In the Measure phase of the DMAIC, an analysis was conducted to evaluate the effectiveness of optimizing the syringe tub scanning process in the aseptic filling area through the implementation of a portable screen mobile scanning system. A comparison was made between the previous process map and the proposed optimization to identify areas of improvement. The previous process map, shown on Figure 2 consisted of four sequential steps, including warehouse dispatch, sanitization with Sporklenz and Isopropyl spray, scanning with a computer and cable scanner, and sanitization with IPA before entering the syringe unpack room. This process was characterized by a linear flow of activities, with each step dependent on the completion of the previous one.

The optimization map introduced a significant enhancement by integrating sanitization with Sporklenz and IPA spray concurrently with the scanning process using a portable mobile scanner (see Figure 3). This modification allowed for the parallel execution of scanning and sanitization, eliminating the need for a separate scanning step and reducing the overall process time. By integrating scanning and sanitization tasks, operators can perform these activities simultaneously, as a result streamlining the workflow and reducing idle time between tasks. This improvement not only increases operational efficiency but also minimizes the risk of contamination during the transfer of syringe tubs between different stages of the process. In addition, the utilization of a portable screen mobile scanning system enables operators to conduct scanning activities directly at the point of sanitization, eliminating the need to transport syringe tubs to a separate scanning station. This not only saves time but also reduces the probability of errors associated with manual data entry or scanning at a different location. However, to guarantee precise and reliable syringe tub scanning, it is imperative to confirm that the portable screen mobile scanning system satisfies all technical specifications. In order to ensure continuous performance and compliance to quality standards, it is also important to develop proper training and standardized operating processes.

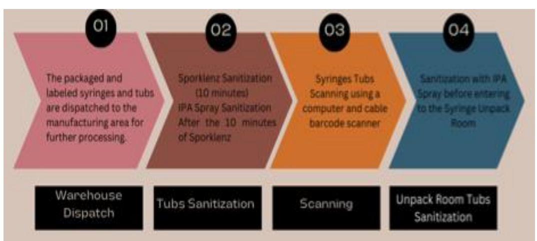

Figure 2

Current Process of Syringe Scanning in the Aseptic Filling Area

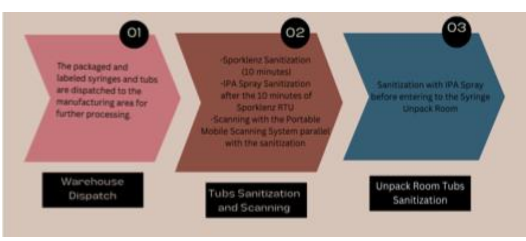

Figure 3

Optimization Process Map of the Syringe Scanning

Analyze Phase

As part of the study about the syringes scanning optimization in the aseptic filling area using the DMAIC methodology, a lead-time analysis was performed. The data corresponds to batches filled in March 2024 .The lead-time was calculated using the following formula: Lead Time (LT) = Total Processing Time + Waiting Time. The Total processing time is defined as the time taken to complete all necessary tasks and activities in the process. In addition, the waiting time is established as the time spent waiting for a task or activity to be completed, including any delays or idle time during the process.

The lead-time analysis conducted on the syringe tub scanning process in the aseptic filling area revealed crucial insights into process efficiency and performance. A total of five batches involving 1,200 tubs, were carefully analyzed in order to determine the impact of mobile scanning implementation on the overall lead-time (see Figure 4). Prior the introduction of mobile scanning, the process involved various stages, including warehouse dispatch, tub sanitization in the Debox area, the scanning process itself, and tub sanitization in the syringe unpack room. These steps collectively contributed to the total lead-time of each batch, as evidenced by the recorded data.

Across the five batches analyzed, lead-time exhibited variability, with durations ranging from 753 to 1019 minutes. The average across all batches was calculated to be approximately 866.2 minutes per batch. This metric provides a starting point to evaluate the process performance and can be employed to determine how well additional optimization strategies succeed. Furthermore, this variability highlights basic difficulties and possible bottlenecks in the scanning process, requiring a systematic strategy to identify and improve areas.

Following the implementation of mobile scanning technology, five test runs were conducted between March 26th and March 30th, 2024, with each run consisting of 1,200 tubs, shown in Figure 5. The lead-time for each test run was significantly reduced compared to the pre-implementation period. The time ranged from 454 to 503 minutes, representing a substantial improvement over the initial lead-time measurements. The comparison between data before and after the implementation of mobile scanning technology highlights the effectiveness of the optimization process. Before implementation (see Figure 6 and Figure 7), lead times ranged from 753 to 1019 minutes, indicating variability and potential inefficiencies in the scanning process. However, after the implementation and optimization of mobile scanning technology, shown in Figure 8, lead times were consistently reduced, with the highest lead-time recorded at 503 minutes, marking a substantial improvement. The results demonstrate the positive impact of mobile scanning technology on the efficiency of the syringe tub scanning process.

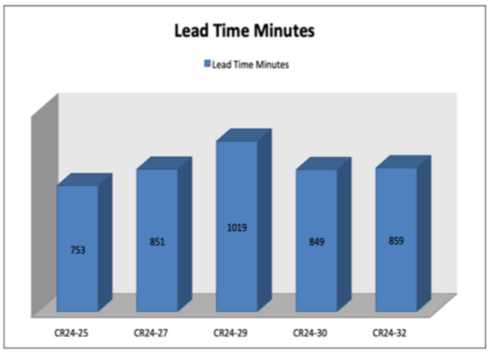

Figure 4

Lead Time Chart of Syringes Scanning Process

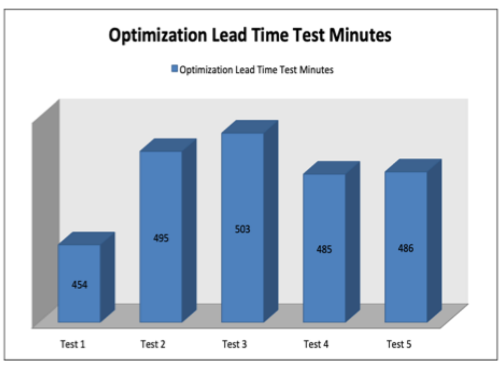

Figure 5

Lead Time Chart of Syringes Scanning Process

Fishbone diagram analysis of syringes tubs scanning process in aseptic filling area shows the influence of factors that affect the efficiency of the process considering the input of all departments within the process (see Figure 9). Machine issues like failure of equipment or MES issues demonstrate the need for regular maintenance as well as system configuration to guarantee accuracy. Inconsistency in methods, like improper automation and standardization, leads to the standardized methods and proper systems integration, as a result.

Material linked issues, including supply chain disruptions, and damaging the tubs, need to be solved by efficient buying practices and effective quality checks in order to prevent them from causing problems.

Date of Scanning	Commodity Description	Scanning Start Time	Scanning End Time	Total Time (Minutes)	Quantity of Tubs
12-Mar-24	BTH Hypak Physiolis Syringe Barrel Fix Needle 29 GA	144	635	291	1200
15-Mar-24	BTH Hypak Physiolis Syringe Barrel Fix Needle 29 GA	355	938	343	1200
20-Mar-24	BTH Hypak Physiolis Syringe Barrel Fix Needle 29 GA	230	1024	474	1200
22-Mar-24	BTH Hypak Physiolis Syringe Barrel Fix Needle 29 GA	620	1127	307	1200
25-Mar-24	BTH Hypak Physiolis Syringe Barrel Fix Needle 29 GA	1128	430	302	1200

Figure 6

Led Time Calculation of the Syringes Tub

Date	Warehouse Dispatch Total Time	Tubs Sanitization Debox Area Total Time (Minutes)	Scanning Total Time (Minutes)	Tubs Sanitization Syringe Unpack Total Time (Minutes)	Total Lead Time (Minutes)
12-Mar-24	30	310	291	122	**753**
15-Mar-24	33	345	343	130	**851**
20-Mar-24	40	365	474	140	**1019**
22-Mar-24	32	379	307	131	**849**
25-Mar-24	30	388	302	139	**859**

Figure 7

Syringes Tubs Scanning Process Lead Time Calculation

Date	Warehouse Dispatch Total Time	Tubs Sanitization Debox Area Total Time (Minutes)	Tubs Sanitization Syringe Unpack Total Time (Minutes)	Total Lead Time (Minutes)
26-Mar-24	30	309	115	454
27-Mar-24	31	335	129	495
28-Mar-24	36	329	138	503
29-Mar-24	32	326	127	485
30-Mar-24	29	333	124	486

Figure 8

Total Led Time Optimization Calculation of Syringes Scanning Process

Personnel connected issues such as training gaps and uncomfortable settings degrade workers' productivity, therefore bringing to the front the need for productive leaders and conductive workplaces. Measurement related problems such as inventory mistakes and performance metrics constitute an obstacle for effective monitoring and performance optimization, highlighting the role of improved inventory management systems and data-driven decision-making. The environmental factors, such as poor lighting and noisy working environments, affect operator efficiency, underscoring the need for workspace enhancements and advanced noise reduction techniques, which ensure workspace health for effective scanning activities.

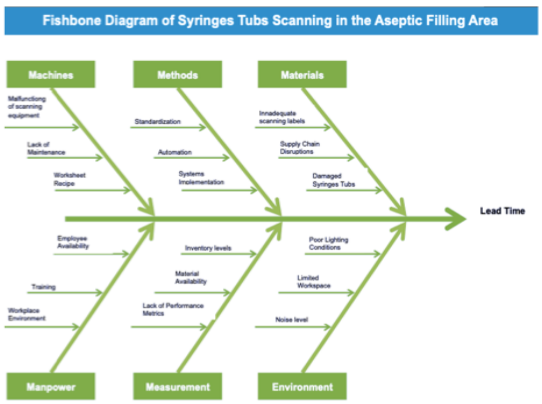

Figure 9
Fishbone Diagram of Syringes Scanning Process

Improve Phase

In the Improve stage of DMAIC methodology, the goal is to implement and test the solution developed during the Analyze step to address the root issues. This step marks the most crucial stage of the continuous improvement process since it requires the conversion of the data analysis insights into practical strategies that will ultimately improve the performance of the syringe tub scanning process in an aseptic filling area. The Improve stage represents a range of sequential measures that target the efficiency of the scanning process to attain the goals quickly and effectively. One of the key strategies in the Improve phase is the implementation of a mobile scanning system equipped with advanced barcode scanning technology. This solution aims to streamline the scanning process by eliminating manual data entry and allowing operators to scan syringe tubs directly at the point of preparation. Standardization of scanning procedures is also crucial during this phase, as it ensures consistency across all scanning activities and minimizes variability, thereby enhancing reliability and accuracy.

Control Phase

In the Control phase of the improvement project aimed at optimizing the syringe tubs scanning process in the aseptic filling area through the implementation of a mobile scanning system, several strategies are being employed to ensure the sustained effectiveness of the process. Firstly, a comprehensive monitoring and measurement plan is being developed to track key performance indicators (KPI's) such as scanning accuracy, cycle time, and error rates. This plan will enable the team to quickly identify any deviations from the desired performance levels and take corrective actions as necessary. In addition, training programs and standardized operating procedures (SOPs) are being developed to guarantee that operators possess the knowledge and abilities needed to perform their tasks consistently and accurately. These protocols will be reinforced during regular training sessions, which will guarantee 100% compliance.

Conclusion

Adopting the comprehensive DMAIC Methodology analysis for improving the scanning process for syringe tubs that are utilized in the aseptic filling area with lead-time reduction as the primary objective has provided remarkable findings and lessons. In addition, the methodology has proven to be a useful tool in understanding process efficiency and performance within a shorter interval of time, mainly by getting rid of the steps that are not necessary and impacts the company metrics. The lead-time analysis in which the data from batches filled in March 2024 illustrated clearly how the mobile scanning system could ensure improved process efficiency. Before the application of a mobile scanning, the process was in multiple stages, which increase the changeover time. Across the five batches examined it was noted that batch Lead-Time displayed a variation with batch time ranging from 753-1019 minutes, thus underscoring potential bottlenecks and steps through the process can be improved. Following the introduction of mobile scanning technology, five test runs was conducted between March 26 and March 30 for which each run comprised of 1200 tubs. Each test run lead-time was dramatically reduced (average of 454-503 minutes) compared to the pre-implementation time, showing a very appreciable improvement. The contrast between the data before and after the introduction of the mobile scanning technology illustrates the optimization process performance. Moving ahead, operational metrics are to be continuously monitored and the processes are to be continuously rectified in order to minimize variability as well as enhance efficiency.

REFERENCES

[1] Sacha, G., Rogers, J. A., & Miller, R. L. (2015). Pre-filled syringes: a review of the history, manufacturing and challenges. Pharmaceutical Development & Technology, 20 (1), 1–11. [Online] Available: https://ezproxy.pupr.edu:2093/10.3109/10837450.2014.982825

[2] Parag V Ingle., Vivekanand Chatap., & Bhatia N.M (2014). Environmental Control of Parenteral Production. Journal of Pharmaceutical Research & Clinical Practice, 4(3), 22-32. [Online] Retrieved from https://www.rroij.com/open-access/environmental-control-for-parenteral-production.pdf

[3] Agalloco, J. P., & Carleton, F. J. (2007). "Validation of Pharmaceutical Processes". CRC Press.

[4] Cottyn, J., Van Landeghem, H., Stockman, K., & Derammelaere, S. (2011). A method to align a manufacturing execution system with Lean objectives. International Journal of Production Research, 49(14), 4397–4413.

[5] Li, Xiaoyan & Liang, Xuedong & Li, Zhi. (2023). "The Strategy of Strengthening Efficiency and Environmental Performance of Product Changeover in the Multiproduct Production System". SAGE Open. 13. 10.1177/21582440231193390.